Office Action Summary	Application No.	Applicant(s)	
	10/005,169	GUENTHER ET AL.	
	Examiner	Art Unit	
	Valerie E. Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to a gene targeting construct and a method of producing the gene targeting construct, classified in class 536, subclass 23.1.

II. Claims 5-7, 9 drawn to a genetically modified animal cell, classified in class 435, subclass 325.

III. Claims 8, 10, 14, 15, 18, 19 drawn to a non-human transgenic animal and methods of making the animal classified in class 800, subclass 21.

IV. Claims 11, 13, 16, 17, 20, 21, 23 drawn to methods of using a non-human, transgenic animal with a disruption in the NOR1 gene to screen for agents that modulate NOR1, and the agent, classified in class 800, subclass 3.

V. Claims 12 and 13 drawn to a method of identifying an agent that modulates NOR1 by contacting the agent to a cell with a disruption in the NOR1 gene and the agent, classified in class 530, subclass 350.

VI. Claims 22 and 23 drawn to a method of identifying an agent that inhibits NOR1, by contacting the agent to a cell that expresses the NOR1gene, and the agent, classified in class 530, subclass 350.

VII. Claims 24 and 25, drawn to a method of treating impaired balance or motor coordination, classified in various classes and subclasses.

VIII. Claim 26, drawn to a pharmaceutical composition containing NOR1, classified in class 514, subclass 2.

L Number	Hits	Search Text	DB	Time stamp
1	267	Nor1 or TEC or NR4A3)and(mutant or knockout	USPAT; US-PGPUB; EPO; JPO; DERWENT	2002/12/02 15:32
2	10973	guenther.in.	USPAT; US-PGPUB; EPO; JPO; DERWENT	2002/12/02 15:33
3	5233625	s guenther.in. and NOR1	USPAT; US-PGPUB; EPO; JPO; DERWENT	2002/12/02 15:33
5	2	guenther.in. and NOR1	USPAT; US-PGPUB; EPO; JPO; DERWENT	2002/12/02 15:34
4	3	allen.in. and NOR1	USPAT; US-PGPUB; EPO; JPO; DERWENT	2002/12/02 15:34
-	7	NOR1 and transgen$	USPAT; US-PGPUB; EPO; JPO; DERWENT	2002/11/06 13:35
-	9	NOR1 and (knockout or (knock adj out) or mutant)	USPAT; US-PGPUB; EPO; JPO; DERWENT	2002/11/06 13:20
-	1	(NOR1 and transgen$) not (NOR1 and (knockout or (knock adj out) or mutant))	USPAT; US-PGPUB; EPO; JPO; DERWENT	2002/11/06 13:35
-	26818	(NOR1 and (knockout or (knock adj out) or mutant)) or TEC or NR4A3	USPAT; US-PGPUB; EPO; JPO; DERWENT	2002/11/06 13:37
-	252	Nor1 or TEC or NR4A3)and(mutant or knockout	USPAT; US-PGPUB; EPO; JPO; DERWENT	2002/11/06 13:38
-	252	Nor1 or TEC or NR4A3)and(mutant or knockout	USPAT; US-PGPUB; EPO; JPO; DERWENT	2002/11/06 13:39
-	53	Nor1 or TEC or NR4A3)and(knockout	USPAT; US-PGPUB; EPO; JPO; DERWENT	2002/11/06 14:00
-	53	Nor1 or TEC or NR4A3)and(knockout	USPAT; US-PGPUB; EPO; JPO; DERWENT	2002/11/06 14:00

Inventions I and II are patentably distinct because, the nucleic acid construct can be used as probe while the cells can be used in in vitro assays of NOR1 function. The protocols and reagents required for the nucleic acid construct and the cells are materially distinct and separate. The burden required to search inventions I and II together would be undue.

Inventions I and III are patentably distinct because the construct group I can be used to transfect cells in vitro while the mouse of invention III can be used as a model of disease. The construct of invention I does not have to be used to make the mouse of invention III, nor does the mouse of invention III require the construct of invention I. The burden required to search inventions I and III together would be undue.

Inventions I and IV, V or VI are patentably distinct because the nucleic acid construct can be used as probe while the methods can be used to identify agents that modulate (Inventions IV and V) or inhibit (Invention VI) NOR1. The protocols and reagents required to make and use the nucleic acid construct are materially distinct from those for the methods of screening compounds. The burden required to search inventions I and V or VI together would be undue.

Inventions I and VII are patentably distinct because the nucleic acid construct can be used as probe while the methods can be used to treat impaired balance or motor coordination. The protocols and reagents required to make and use the nucleic acid construct are materially distinct from those for the methods of treatment. The burden required to search Inventions I and VII together would be undue.

Inventions I-VI or VII and Invention VIII are patentably distinct because the nucleic acid construct of Invention I, the cells of Invention II, the transgenics of Invention III, the NOR1 modulators of inventions IV- VI and the method of treatment of Invention VII are not necessary

for the pharmaceutical composition and the pharmaceutical composition is not needed for the Inventions I-VII. The protocols and reagents required for Inventions I-VII are materially distinct from those for the pharmaceutical of Invention VIII. The burden required to search Inventions I-VII and Invention VIII together would be undue.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the transgenic animals and methods of making the animals of invention III do not necessarily require the cells of invention II and the cells can be used for distinctly different processes such as screening compounds. The burden required to search invention II and III together would be undue.

Inventions II and IV are patentably distinct because the cells of Invention II can be used in vitro to determine the effects of a NOR1 disruption on gene expression while the methods of Invention IV can be used to identify agents that modulate NOR1 expression in vivo. The cells are not needed for the methods and the methods are not required for the cells. The burden required to search inventions II and IV together would be undue.

Inventions II and V or VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case agents that modulate NOR1 expression or activity can be

identified using transgenic animals or in vitro protein and DNA binding experiments while the cells of invention II can be used in differential expression assays. The burden required to search inventions II and V or VI together would be undue

Inventions II and VII are patentably distinct because the cells can be used to make protein or test gene expression while the methods can be used to treat disease. The cells are not necessary for the methods nor are the methods necessary for the cells. The burden required to search Inventions II and VII together would be undue.

Inventions III and IV are related as product and process of use. In the instant case agents can be identified in vitro using cells deficient of NOR1 and the transgenic animals can be used for phenotypic analysis. The burden required to search inventions III and IV together would be undue.

Inventions III and V or VI are patentably distinct because the transgenics of Invention III can be used as an in vivo disease model while the methods of Invention V and VI can be used to identify an agent. The transgenic animals are not needed for the methods of using the cells and the methods are not needed for the transgenics. The burden required to search inventions III and V or VI together would be undue.

Inventions III and VII are patentably distinct because the transgenic of Invention III can be used as an in vivo disease model while the methods of Invention VII can be used to treat disease. The transgenic animals are not needed for method of treatment and the method of treatment are not needed for the transgenics. The burden required to search invention III and VII together would be undue.

Inventions IV and V or VI are patentably distinct because the methods of Invention IV are materially different from the methods of Inventions V and VI. The methods of invention IV make use of transgenic animals while Inventions V and VI use cells. Invention IV is not needed for Invention V or VI and Invention V or VI is not needed for invention IV. The burden required to search inventions IV and V or VI together would be undue.

Inventions IV, V or VI and VII are patentably distinct because the methods of Inventions IV, V, and VI can be used to identify modulators of NOR1 while the methods of Invention VII can be used to treat impaired balance or motor coordination. The burden required to search Inventions IV, V, or VI and VII together would be undue.

Inventions V and VI are patentably distinct because each is directed to products that differ considerably in composition, structure and function. Invention V is directed to modulators of NOR1 expression or activity while Invention VI is directed specifically to inhibitors of NOR1 activity. Furthermore, the modulators are not necessary for the inhibitors and the inhibitors are not necessary for the modulators. The burden required to search Inventions V and VI together would be undue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Valarie Bertoglio
Patent Examiner

MICHAEL C. WILSON
PATENT EXAMINER